REMARKS

This Response, filed in reply to the Office Action dated July 10, 2007, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-21 are currently pending in the application, of which Claims 3-6, 13 and 18-21 are withdrawn from consideration as being directed to nonelected inventions. Claims 1, 2, 7-12 and 14-17 are rejected. Claims 1, 2, 7-12 and 14 are objected to. Claims 5, 6, 20 and 21 are canceled. Claims 3, 4, 12, 13, 15, 18 and 19 are currently amended and entry of these amendments is respectfully requested. Support for these claim amendments can be found throughout the specification, and at least on pages 3, 10 and 27 of the originally filed specification. Claims 3, 4, 18 and 19 have been amended to better capture Applicants intended invention, and Applicants respectfully request rejoinder of these method claims should the corresponding generic linking claim be found allowable. Upon entry of these amendments, Claims 1-4 and 7-19 will be pending in the Application.

Claim Rejections Under 35 U.S.C. § 112, for Lack of Enablement

On page 2 of the Office Action, Claims 1, 2, 7-12 and 14-17 are rejected under 35 U.S.C. § 112, for allegedly lacking enablement. The Office Action asserts that "the specification, while being enabling for P2Y12 and platelet aggregation inhibition activity for a select compound of the elected subject matter, does not reasonably provide enablement for P2Y12 and platelet

aggregation inhibition for all elected compounds and pharmaceutical compositions." The Office Action alleges that the claimed invention lacks enablement because none of the elected compounds of formula (I) have been shown to inhibit platelet aggregation, therefore the testing for such inhibition would be substantial. Further, the Office Action alleges that the specification does not provide details as to how to determine the degree of platelet inhibition.

Applicants respectfully disagree with the rejection, and submit that the specification is enabling not only for the elected compound, but for all the claimed compounds encompassed by elected Group IV, in view of the following remarks.

Applicants respectfully submit that one of ordinary skill in the art would understand that quinolone derivatives possessing P2Y12 inhibitory activity would also be expected to possess platelet aggregation inhibitory activity because the state of the art establishes the criticality of P2Y12 inhibitory activity for inhibition of platelet aggregation. On page 3 of the Office Action, the Office admits as much, asserting that a review of the literature "suggests that P2Y12 inhibition is the critical feature of platelet aggregation inhibitors" (emphasis added). Accordingly, one of ordinary skill in the art would understand that P2Y12 inhibitory activity is the fundamental activity shared by inhibitors of platelet aggregation, and therefore, compounds exhibiting P2Y12 inhibitory activity would also be expected to possess platelet aggregation inhibitory activity. In Table 2, on page 29 of the originally-filed specification, eighteen (18) quinolone derivatives are described which differ in the substituents at the R^2, R^5, R^{11}, R^{12} and Y groups, yet all of these compounds exhibit potent P2Y12 inhibitory activity. Thus, in view of the

above remarks, one of ordinary skill in the art would predict that the claimed quinolone derivatives having different substituents at the R^2, R^5, R^{11}, R^{12} and Y groups possess platelet-aggregation inhibitory activity.

On page 7 of the Office Action, the Office admits that compounds wherein X = C-R^7 (R^7 = H), Y = C-R^6 (R^6 = H), R^2 = straight or branched chain alkyl, R^3 = halogen, R^4 = cyclohexyl, R^5 = hydrogen, R^{11} = hydrogen, R^{12} = straight or branched chain alkyl mono-substituted with -CO_2H are enabled. In this regard, Applicants attach herewith a Rule 1.132 Declaration to establish that, in addition to Applicants' elected compound, other quinolone derivatives of elected Group IV which differ with regard to the substituents at the R^{12} and R^2 groups also possess both platelet aggregation-inhibitory activity and P2Y12 inhibitory activity. For example, the data in the Declaration establishes that for non-elected compounds of Group IV, wherein the R^{12} group contains hydroxyl, phenyl, pyridyl, -CO_2R^0, or -$C(O)N(R^0)_2$ substituents, both potent P2Y12 inhibitory activity and platelet aggregation-inhibiting activity is observed. Moreover, the Declaration clearly shows that compounds in which the R^2 group is either a lower alkyl or a cycloalkyl exhibit both potent platelet aggregation-inhibitory activity and P2Y12 inhibitory activity. Accordingly, Applicants respectfully submit that a sufficient number of quinolone derivatives of elected Group IV possessing both P2Y12 inhibitory activity and platelet aggregation-inhibiting activity are disclosed such that one of ordinary skill in the art would understand how to make and use the claimed invention.

With regard to the Office Action's assertion that "[s]pecifics of the factors used in the calculated percent inhibition are not discussed in terms of 100% and 0% limits", Applicants respectfully submit that on pages 27-28 of the originally filed specification, specific assays for determining platelet aggregation-inhibiting activity are explicitly described. For example, from reading the instant specification, one of skill in the art would understand that 100% inhibition is determined by adding ADP and a quinolone derivative to the reaction and plotting platelet aggregation, wherein 100% inhibition can be determined when the area under the curve is equal to zero. Conversely, 0% inhibition may obviously be determined by the addition of ADP whilst omitting any inhibitors of platelet aggregation from the reaction, such as quinolone derivatives. For the determination of the inhibition activity of P2Y12 and 2-MeS-ADP binding, page 29, lines 1-6 of the specification as filed describes in detail how the 0% and 100% control values are obtained, such that one of ordinary skill in the art would fully understand how these limits are defined. Thus, Applicants respectfully submit that one of ordinary skill in the art would clearly understand the meanings of "0%" and "100%", and how they are derived, from reading the instant specification. Further, Applicants assert that calculation of the 0% and 100% inhibition values is not an essential part of the claimed invention, and that it would be well within the grasp of one of ordinary skill in the art to design an assay for determining either P2Y12 inhibitory activity or platelet aggregation inhibitory activity even in the absence of guidance from the specification.

Withdrawal of this rejection is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, for Indefiniteness

On page 5 of the Office Action, Claims 12 and 15-17 are rejected under 35 U.S.C. § 112, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office Action alleges that the assignment of R^{12} as a "lower alkyl" in Claim 12 is unclear, as a proviso reads that the lower alkyl is substituted with one or more groups selected from the group Q, provided that at least one is substituted with a group of the Group P. The Office Action contends that the claim, as written, does not make clear whether the substituent from Group Q must be substituted with a substituent from Group P, or if one substituent must come from Group P if more than one substituent is selected.

Solely to advance prosecution, Applicants hereby voluntarily amend Claim 12 to better clarify Applicants' intended invention. Applicants respectfully submit that currently presented Claim 12 clearly recites that if R^{12} is a lower alkyl substituted with one or more groups selected from Group Q, then at least one of these groups must be selected from Group P. In the case where R^{12} is a lower alkyl substituted with one group selected from Group Q, this group must be selected from Group P. Applicants submit that the amendments to Claim 12 render the rejection moot.

With regard to Claim 15, the Office Action contends that there is insufficient antecedent basis for recitation of "the pharmaceutical composition" in Claim 15. Solely to advance

prosecution, Applicants hereby amend Claim 15 to recite "a pharmaceutical composition." Applicants submit that the amendment to Claim 15 provided herewith overcomes the rejection.

The Office Action further rejects Claim 15 and rejects Claims 16 and 17 because it is alleges that insufficient antecedent basis exists for recitation of "according to any one of claims 7 through 14" in Claims 15-17, since Claim 13 has been withdrawn from consideration as being directed to a non-elected invention.

Applicants respectfully submit that the rejection is improper because although Claim 13 does not contain subject matter which encompasses the elected species, Claim 13 does encompass other non-elected species of elected Group IV. Applicants point out that an Election of Species requirement is issued for the purpose of patentability searching, and should the elected species be found not to be anticipated or rendered obvious by prior art, the claims should be further examined with respect to other non-elected species to determine patentability, pursuant to MPEP 803.02. As no prior art rejections have been made of record, and the Office Action indicated that the elected species is allowable subject matter, Applicants respectfully request that the rejection of Claim 13 be withdrawn and that Claim 13 be fully examined to determine patentability with regard to the non-elected species of Group IV.

Withdrawal of this rejection is therefore respectfully requested.

Claim Objections

The Office Action objects to Claims 1, 2, 7-9, 11-12 and 14 because the claims allegedly contain subject matter outside the elected Group IV subject matter. Further, the Office Action objects to Claims 8, 9 and 11 under 37 CFR § 1.75 as being substantial duplicates of Claim 7. Similarly, Claim 10 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants respectfully disagree with the objections to the claims. As mentioned above, should the subject matter of the elected species be found not to be anticipated or rendered obvious by prior art, the claims that read on the elected group should be examined with respect to other non-elected species. As no prior art rejections have been made of record, and the Office Action indicated that the elected species is allowable subject matter, Applicants respectfully request that the claim objections be withdrawn and that the claims be fully examined to determine patentability with regard to the non-elected species of Group IV.

Withdrawal of this objection is therefore respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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